

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: JENKINS et al.

Appln. No.: 09/777,979

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Title: MEDICAL IMPLANT FOR ELECTRO-  
STIMULATION USING DISCRETE  
MICRO-ELECTRODES

Group  
Art Unit: 3754

Examiner: Nicolas, Frederick C.

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BY: D. G.

APPENDIX TO AMENDMENT A

Hon. Commissioner of Patents and Trademarks  
ATTENTION: Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. §1.121, Applicants present herewith marked-up text of the specification and claims of this application as amended by the foregoing amendment:

**IN THE SPECIFICATION:**

Please replace the paragraph beginning at page 12, line 23, with the following rewritten paragraph:

– The present invention also provides a method for electrostimulation of gastrointestinal tissue, said method comprising

(a) inserting an implant device through a trocar into the endo-[abdominal] abdominal cavity, wherein the implant device has a plurality of micro-electrodes and an electrical connection terminal for connection to an electrical pulse generator,

wherein various pairs of the micro-electrodes can be electrically connected to the electrical connection terminal,

(b) positioning the plurality of micro-electrodes within an area of the gastrointestinal track to provide electrical stimulation to the gastrointestinal tissue to be electrostimulated,

(c) immobilizing the implant device so as to maintain good electrical stimulation of the gastrointestinal tissue to be electrostimulated during a treatment regime,

(d) attaching the electrical pulse generator to the electrical connection terminal of the implant device,

(e) delivering electrical impulses to the implant device whereby various pairs of the plurality of micro-electrodes can be tested for electrical stimulation of the gastrointestinal tissue to be electrostimulated,

(f) selecting a pulsing micro-electrode and a receiving micro-electrode from the various pairs of the plurality of micro-electrodes tested in step (e) to provide the good electrical stimulation of the of the gastrointestinal tissue to be electrostimulated, and

(g) using the selected pulsing micro-electrode and received micro-electrode to electrostimulate the [gastrointestinal] gastrointestinal tissue. Preferably the gastrointestinal tissue subjected to electrostimulation is associated with the Auerbach plexus and/or the Meissner plexus. –

Please replace the paragraph beginning at page 13, line 20, with the following rewritten paragraph:

– The present invention also provides a method for clinically effective electrostimulation of gastrointestinal tissue, said method comprising

(a) implanting an implant device in the endo-[adominal] abdominal cavity, wherein the implant device has a plurality of micro-electrodes and an electrical connection terminal for connection to an electrical pulse generator, wherein various

pairs of the micro-electrodes can be electrically connected to the electrical connection terminal,

(b) positioning the plurality of micro-electrodes within an area of gastrointestinal track to provide electrical stimulation to the gastrointestinal tissue to be electrostimulated,

(c) immobilizing the implant device so as to maintain good electrical stimulation of the gastrointestinal tissue to be electrostimulated during a treatment regime,

(d) attaching the electrical pulse generator to the electrical connection terminal of the implant device,

(e) delivering electrical impulses to the implant device whereby various pairs of the plurality of micro-electrodes can be tested,

(f) measuring the impedance between the various pairs of the plurality of micro-electrodes,

(g) selecting a pulsing micro-electrode and a receiving micro-electrode from the various pairs of the plurality of micro-electrodes tested in step (e), wherein the selected pulsing micro-electrode and the selected receiving micro-electrode pair has the lowest, or close to the lowest, impedance measured in step (f), and

(h) providing electrostimulation of the gastrointestinal tissue using the selected pulsing micro-electrode and the selected receiving micro-electrode pair. In an especially preferred method, the impedance is automatically measured between the various pairs of the plurality of micro-electrodes periodically (e.g., once an hour, once every four hours, once every twelve hours, once a day, or the like) to identify and select the micro-electrode and the receiving micro-electrode pair having the lowest impedance to provide good electrostimulation to the tissue to be stimulated over time. Should the implant device shift within the penetration tunnel, this method would allow a new and more effective micro-electrode pair to be selected at the next periodic measuring time or interval. —

Please replace the paragraph beginning at page 16, line 20, with the following rewritten paragraph:

– Figure 5 illustrates other embodiments of the implant device according to this invention which is especially designed for electrostimulation and/or monitoring of [gastrointestinal] gastrointestinal tissue. Panel A shows the penetration device attached to the elongated body whereas Panel B shows the penetration device removed. Panel C illustrates a portion of the implant device having micro-electrodes which encircle the elongated body between the immobilizing units. –

Please replace the paragraph beginning at page 21, line 4, with the following rewritten paragraph:

– Figure 5 illustrates an implant device with micro-electrodes 16 especially adapted for use in electrostimulation and/or monitoring of other tissue such as, for example, [gastrointestinal] gastrointestinal tissue. In this implant device, the micro-electrodes 16 are located along the elongated body 10 and between the immobilizing mechanisms 36 and 38 (used to secure it to the gastrointestinal wall) such that the micro-electrodes 16 are electrically connected to an electrical connection terminal 26 for connection to a power source (not shown) via multiplexer or switching mechanism 20. The implant device also has a mechanism 30 to penetrate the gastrointestinal wall and a quick release connecting mechanism 40 to separate the penetration device 30 from the elongated body once the device is properly situated. Figure 5A illustrates the implant device with the penetration mechanism 30 attached to the distal end 12; Figure 5B illustrates the implant device once the penetration device 30 is detached, along line 42, from the elongated body. Figure 5C illustrates a portion of the elongated body 10 between the immobilizing units 36 and 38 wherein the micro-electrodes 16 surround or encircle the elongated body 10. Figures 6A, 6B, and 6C illustrate placement of the implant device within the penetration tunnel 50 formed in the tissue to be treated using the penetration device 30 (which has been detached). –

Please replace the paragraph beginning at page 26, line 28, with the following rewritten paragraph:

– As those skilled in the art will understand, the micro-electrodes can be used with a wide variety of implant devices or electrocatheters. Moreover, the immobilizing mechanisms can include, for example, tines, clamps, sutures, a flexible attachment member which can be folded back on the elongated body and attached to the elongated body thereby forming a closed loop around the tissue to be treated, and other locking devices. By “looping” around the tissue of interest, the attachment member and the elongated body are securely attached to the tissue and will resist displacement even in cases where the tissue is subject to vigorous peristaltic movement within the body (e.g., digestive organs). Other [electrocaterers] electrocatheters and/or immobilizing mechanisms are described in greater detail in U.S. Patent 5,423,872 (June 13, 1995); United States Patent Applications Serial Numbers 09/122,832 (filed July 27, 1998), 09/358,955 (filed July 22, 1999), 09/424,324 (filed November 19, 1999), and 09/ 482,369 (filed January 13, 2000); Patent Cooperation Treaty Application No. 98US98/10402 (filed May 21, 1998); and United States Provisional Application Serial Number 60/151,459 (filed August 30, 1999), all of which are hereby incorporated by reference in their entireties. Any of these earlier described implant devices can be easily modified to include the micro-electrodes of the present invention. –

**IN THE CLAIMS:**

Please cancel claims 8-15 without prejudice.

Please amend claims 1, 19, 24, 27, 35, and 41 as follows:

1. (Once amended) An implant device especially adapted for treatment of neuroglial or neuro-muscular tissue, said implant device comprising (1) an elongated body with a distal end and a proximal end; (2) a plurality of micro-electrodes at the distal end; (3) an electric connection terminal at the proximal end for connection to a power source; (4) a plurality of electrical conductors extending through the elongated body from the distal end to the proximal end, wherein each electrical conductor is attached to a single micro-electrode at the distal end, whereby any selected pair of

the plurality of micro-electrodes can be electrically connected to the electric connection terminal to form an electrical pathway between the electric connection terminal, the selected pair of the plurality of micro-electrodes, and the neuroglial or neuro-muscular tissue to be treated; and (5) a multiplexer or switching device to measure impedance between [such that] the selected pair of the plurality of micro-electrodes in order to determine a satisfactory pair of the plurality of micro-electrodes [can be used] to form the electrical pathway.

19. (once amended) The method as in Claim 16, wherein [the] a multiplexer or switching device [comprises] comprising a computer chip is used to select the pulsing micro-electrode and the receiving micro-electrode in step (e).

24. (once amended) A method for clinically effective electrostimulation of gastrointestinal tissue within a patient's endo-abdominal cavity, said method comprising

(a) inserting an implant device [though] through a trocar into the endo-[adominal] abdominal cavity, wherein the implant device has a plurality of micro-electrodes and an electrical connection terminal for connection to an electrical pulse generator, wherein various pairs of the micro-electrodes can be electrically connected to the electrical connection terminal,

(b) positioning the plurality of micro-electrodes within an area of gastrointestinal track to provide electrical stimulation to the gastrointestinal tissue to be electrostimulated,

(c) immobilizing the implant device so as to maintain good electrical stimulation of the gastrointestinal tissue to be electrostimulated during a treatment regime,

(d) attaching the electrical pulse generator to the electrical connection terminal of the implant device,

(e) delivering electrical impulses to the implant device whereby various pairs of the plurality of micro-electrodes can be tested for electrical stimulation of the gastrointestinal tissue to be electrostimulated,

(f) selecting a pulsing micro-electrode and a receiving micro-electrode from the various pairs of the plurality of micro-electrodes tested in step (e) to provide clinically effective electrical stimulation of the of the gastrointestinal tissue to be electrostimulated, and

(g) using the selected pulsing micro-electrode and received micro-electrode to electrostimulate the [gastrointestinal] gastrointestinal tissue.

27. (once amended) The method as in Claim 25, wherein [the] a multiplexer or switching device [comprises] comprising a computer chip is used to select the pulsing micro-electrode and the receiving micro-electrode in step (f).

35. (once amended) A method for clinically effective electrostimulation of gastrointestinal tissue within a patient's endo-abdominal cavity, said method comprising

(a) implanting an implant device in the endo-[adominal] abdominal cavity, wherein the implant device has a plurality of micro-electrodes and an electrical connection terminal for connection to an electrical pulse generator, wherein various pairs of the micro-electrodes can be electrically connected to the electrical connection terminal,

(b) positioning the plurality of micro-electrodes within an area of gastrointestinal track to provide electrical stimulation to the gastrointestinal tissue to be electrostimulated,

(c) immobilizing the implant device so as to maintain good electrical stimulation of the gastrointestinal tissue to be electrostimulated during a treatment regime,

(d) attaching the electrical pulse generator to the electrical connection terminal of the implant device,

(e) delivering electrical impulses to the implant device whereby various pairs of the plurality of micro-electrodes can be tested,

(f) measuring [the] impedance between the various pairs of the plurality of micro-electrodes,

(g) selecting a pulsing micro-electrode and a receiving micro-electrode from the various pairs of the plurality of micro-electrodes tested in step (e), wherein the selected pulsing micro-electrode and the selected receiving micro-electrode pair has the lowest, or close to the lowest, impedance measured in step (f), and

(h) providing electrostimulation of the gastrointestinal tissue using the selected pulsing micro-electrode and the selected receiving micro-electrode pair.

41. (once amended) A method for clinically effective electrostimulation of neuroglial or neuro-muscular tissue, said method comprising

(a) positioning an implant device having a distal end and a proximal end such that the distal end can provide electrical stimulation of the neuroglial or neuro-muscular tissue, wherein the distal end of the implant device has a plurality of micro-electrodes and the proximal end of the implant device has an electrical connection terminal for connection to an electrical pulse generator, and wherein various pairs of the micro-electrodes can be electrically connected to the electrical connection terminal,

(b) positioning the distal end of the implant device sufficiently close to the neuroglial or neuro-muscular tissue to be electrostimulated,

(c) attaching the electrical pulse generator to the electrical connection terminal of the implant device,

(d) delivering electrical impulses to the implant device whereby various pairs of the plurality of micro-electrodes can be tested for electrostimulation of the neuroglial or neuro-muscular tissue, and

(e) measuring [the] impedance between the various pairs of the plurality of micro-electrodes;

(f) selecting a pulsing micro-electrode and a receiving micro-electrode from the various pairs of the plurality of micro-electrodes tested in step (d), wherein the selected pulsing micro-electrode and the selected receiving micro-electrode pair has the lowest, or close to the lowest, impedance measured in step (e); and




(g) providing electrostimulation of the neuroglial or neuro-muscular tissue using the selected pulsing micro-electrode and the selected receiving micro-electrode pair.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

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